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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,355	06/23/2003	Anthony David Auffret	PC22039A	7465
28940	7590	03/13/2006	EXAMINER	
AGOURON PHARMACEUTICALS, INC.			CHUNG, SUSANNAH LEE	
10777 SCIENCE CENTER DRIVE			ART UNIT	
SAN DIEGO, CA 92121			PAPER NUMBER	

1626

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/601,355	Applicant(s) AUFFRET ET AL.	
	Examiner Susannah Chung	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-24 is/are pending in the application.
- 4a) Of the above claim(s) 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/2/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 20-24 are pending in the instant application. Claim 1-19 have been canceled.

Priority

This application claims benefit of 60/399,491, filed on 07/29/2002.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) by application no. 0216515.7 filed in the United Kingdom Patent Office on 07/06/2002, which papers have been placed of record in the file. The application names an inventor or inventors named in the prior application.

Information Disclosure Statement

The information disclosure statement (IDS), filed on 09/02/2003 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Response to Election/Restrictions

Applicant's election *with traverse* of Group I in the reply filed on 01/20/2006 is acknowledged.

The traversal is on the ground that restriction is not proper because it would not be burdensome on Examiner. Examiner will rejoin Group II with Group I and search Claims 20-23 directed to the products of fosfluconazole, but will not examine Claim 24 directed to the process of making the fosfluconazole at this point in the examination process. If the claimed products are allowable, the process of making this product (Claim 24) will be rejoined.

Therefore, for the above reasons, the requirement is upheld in part and is made FINAL.

Scope of the Elected Invention

Claims 20-24 are pending in this application.

The scope of the elected subject matter that will be examined and searched is as follows.

Claims 20-23 directed to a stable disodium salt of fosfluconazole in the form of its trihydrate, its

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hexahydrate, or as a mixture of tri- and hexahydrates, wherein the trihydrate has a water content of about 11% w/w and the hexahydrate has a water content of about 20% w/w or wherein said mixture has a water content from about 11% w/w to about 20% w/w.

Scope of Withdrawn Subject Matter

Claim 24 is withdrawn from further consideration by the examiner, 37 C.F.R. §1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

Claim 24 will be rejoined if any one of Claims 20-23 are found allowable.

Obviousness Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 2 of U.S. Patent Num. 6,977,302 ('302 Patent).

Instant claims 20-23 disclose a stable disodium salt of fosfluconazole in the form of its trihydrate, its hexahydrate, or as a mixture of tri- and hexahydrates, wherein the trihydrate has a water content of about 11% w/w and the hexahydrate has a water content of about 20% w/w or wherein said mixture has a water content from about 11% w/w to about 20% w/w.

Determination of the scope and content of the prior art (MPEP § 2141.01)

'302 Patent Claim 2 teaches a compound which is: alkali metal salt of 2-(2,4-difluorophenyl)-1,3-bis(1H-1,2,4-triazol-1-yl)-2-propyl dihydrogen phosphate (i.e. fosfluconazole).

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The difference between '302 Patent and the instantly claimed compounds is that '302 Patent discloses an alkali metal salt (i.e. lithium, sodium, potassium, rubidium, cesium, francium) of fosfluconazole, while the instantly claimed compounds claim sodium only with specific water weights of the mixtures.

Finding of prima facie obviousness – rationale and motivation (MPEP § 2142-2413)

Although the conflicting claims are not identical, they are not patentably distinct from each other. The '302 Patent claims alkali metal salts, but the working examples in the specification are all directed to the disodium salts of fosfluconazole. The '302 Patent does not disclose specific water weight, but an absence of the water weight does not mean that it is different from the instantly claimed compound. Rather, one can assume that disodium salts of the '302 Patent are inherently the same as the disodium salts claimed in the instant application and would therefore have the same water weight.

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Generally, specific water weights of a salt of a known compound are not a good measure of patentability as water weight can change based on the level of impurity, water in the compound, humidity in the air, etc.... Applicant did not provide any data in the specification, which demonstrates that the instantly claimed disodium compound is not obvious over the compound in the '302 Patent.

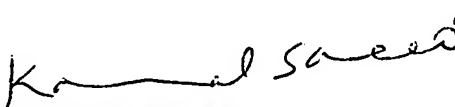
Therefore, one skilled in the art would have found this variation obvious when faced with '302 Patent because both compounds claim the same disodium salt of fosfluconazole, so one skilled in the art would expect similar properties and results.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

Susannah Chung
Patent Examiner, AU 1626
Date: 03/02/2006